

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Eric G. Lovett et al.

Examiner: George R. Evanisko

Serial No.: 10/017,800

Group Art Unit: 3762

Filed: December 12, 2001

Docket: 279.353US1

For: RATE SMOOTHING CONTROL

Assignee: Cardiac Pacemakers, Inc.

APPEAL BRIEF UNDER 37 CFR § 41.37

Mail Stop Appeal Brief- Patents
Commissioner for Patents
P.O. Box 1450
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Sir:

The Appeal Brief is presented in support of the Notice of Appeal to the Board of Patent Appeals and Interferences filed on June 26, 2006, from the Final Rejection of claims 1-6, 15-20, and 28-32 of the above-identified application, as set forth in the Final Office Action dated February 24, 2006 (hereinafter "the Office Action").

The Commissioner of Patents and Trademarks is hereby authorized to charge Deposit Account No. 19-0743 in the amount of 500.00 which represents the requisite fee set forth in 37 C.F.R. § 41.2(b)(2). Appellant respectfully requests consideration and reversal of the Examiner's rejections of pending claims.

1. REAL PARTY IN INTEREST

The real party in interest of the above-captioned patent application is the assignee, CARDIAC PACEMAKERS, INC., owned solely by GUIDANT CORPORATION, which recently merged with BOSTON SCIENTIFIC CORPORATION.

2. RELATED APPEALS AND INTERFERENCE

There are no other appeals or interferences known to Appellant that will have a bearing on the Board's decision in the present appeal.

3. STATUS OF THE CLAIMS

The present application was filed on December 12, 2001 with claims 1-43. Claims 1-36 remain pending. Claims 7-14, 21-27 and 33-36 stand withdrawn. Claims 37-43 were previously canceled. Claims 1-6, 15-20, and 28-32 stand rejected and are the subject of the present Appeal. The grounds of the rejection are set forth in Section 6 below.

4. STATUS OF AMENDMENTS

No amendments have been made subsequent to the Final Office Action dated February 24, 2006.

5. SUMMARY OF CLAIMED SUBJECT MATTER

The claims that are the subject of this Appeal include independent claims 1, 16, and 32. Claims 1 recites a system, and claim 16 and 32 each recite a method. The following summary does not provide an exhaustive or exclusive view of the claimed subject matter, and Appellant refers to the appended claims for a complete statement of the claimed subject matter. References to the specification and drawings are provided as

examples, and are not intended to indicate that these references are the only references from the specification and drawings that can be applied to the claims.

Independent Claim 1

Claim 1 recites a system. The recited system (700 in FIGS. 7-9) includes a signal input circuit (710 in FIGS. 7-9) and a controller circuit (720 in FIGS. 7-9). The signal input circuit includes at least one of a cardiac sense amplifier (712 in FIGS. 7-9) and a sensor (911 in FIG. 9). The cardiac sense amplifier is adapted to monitor a cardiac signal. The sensor is adapted to monitor a physiologic parameter. The controller circuit includes a predetermined state detector (730 in FIGS. 7-9) and a rate smoothing module (750 in FIGS. 7-9). The predetermined state detector is coupled to the signal input circuit and adapted to detect a predetermined state from the at least one of the cardiac signal and the physiologic parameter. The predetermined state includes at least one of a heart rate state, a cardiac rhythm state, a patient activity state, a respiration state, and a metabolic need state (page 18, lines 13-27; page 19, lines 17-22; page 20 lines 11-12; page 20, line 21-page 21, line 0). The rate smoothing module is coupled to the predetermined state detector and includes at least one rate smoothing algorithm (page 17, lines 18-19). The rate smoothing module is configured to select a first rate smoothing percentage and a second rate smoothing percentage of the rate smoothing algorithm based on whether the predetermined state is present (page 19, lines 0-7). The first rate smoothing percentage limits a degree of pacing rate increase, and the second rate smoothing percentage limits a degree of pacing rate drop (page 17, line 21-27).

Independent Claim 16

Claim 16 recites a method. The recited method (FIGS. 10-12) includes monitoring at least one of a cardiac signal and a physiologic parameter. The cardiac signal is monitored using a cardiac sense amplifier of an implantable system. The physiologic parameter is sensed using a sensor of the implantable system. The recited method further includes determining whether a state of the at least one of the cardiac

signal and the physiologic parameter corresponds to a predetermined state using the implantable system (1020 in FIG. 10; 1120 in FIG. 11; 1220 in FIG. 12). The predetermined state includes at least one of a heart rate state, a cardiac rhythm state, a patient activity level state, a respiration state, and a metabolic need state (page 22, lines 1-4 and lines 10-15; page 22, line 23-page 23, line 2). The recited method further includes selecting a first rate smoothing percentage and a second rate smoothing percentage of a rate smoothing algorithm using the implantable system if the state of the at least one of the cardiac signal and the physiologic parameter corresponds to the predetermined state (1060 in FIG. 10; 1160 in FIG. 11; 1260 in FIG. 12). The first rate smoothing percentage limits a speed of pacing rate increase, and the second rate smoothing percentage limits a speed of pacing rate drop (page 17, line 21-27).

Independent Claim 32

Claim 32 recites a method. The recited method (FIG. 10) includes monitoring a cardiac signal using a cardiac sense amplifier of an implantable system (1000 in FIG. 10), and determining whether a state of the cardiac signal corresponds to at least one predetermined heart rate state using the implantable system (1020 in FIG. 10). The recited method further includes selecting a first rate smoothing percentage and a second rate smoothing percentage of a rate smoothing algorithm using the implantable system if the state of the cardiac signal corresponds to the at least one predetermined heart rate state (1060 in FIG. 10). The first rate smoothing percentage limits a speed of pacing rate increase, and the second rate smoothing percentage limits a speed of pacing rate drop (page 17, line 21-27).

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1-6, 15-20, and 28-32 were rejected under 35 U.S.C. § 103(a) as being unpatentable over “Contak TR CHFD” System Guide in view of Stroebel et al. (U.S. Patent No. 5,725,561).

7. ARGUMENT

The Office Action includes §103 rejections. Appellant traversed these rejections, asserting that the §103 rejections fail to provide a *prima facie* case. The Patent and Trademark Office failed to adequately address the traversal. In the following argument, the requirements for a §103 rejection are provided first, and then the §103 rejections are discussed.

A. Requirements for a §103 Rejection

MPEP §§2142-43 identifies the requirement for a *prima facie* case of obviousness: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference (or references when combined) must teach or suggest all the claim limitations. *See also In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Prior Art Reference(s) Must Teach Or Suggest All The Claim Limitations

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). “All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).”

Suggestion Or Motivation To Modify The Reference Or Combine References

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. “The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art.” *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000). See also *In re Lee*, 277 F.3d 1338, 1342-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002) (discussing the importance of relying on objective evidence and making specific factual findings with respect to the motivation to combine references); *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

“The factual inquiry whether to combine references must be thorough and searching. It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions and cannot be dispensed with.” *Lee*, at 1343. “[The] factual question of motivation to combine is material to patentability, and could not be resolved on subjective belief and unknown authority.” *Lee*, at 1343-44. “The board cannot rely on conclusory statement when dealing with particular combinations of prior art and specific claims, but must set forth the rationale on which it relies.” *Lee*, at 1343. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).

Dependent Claims

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

B. The Office Action Fails To Make A *Prima Facie* Case Of Obviousness For The §103 Rejections.

Claims 1-6, 15-20, and 28-32 were rejected under 35 U.S.C. § 103(a) as being unpatentable over GUIDANT CORPORATION's "Contak TR CHFD" System Guide (hereinafter "the System Guide") in view of Stroebel et al. (U.S. Patent No. 5,725,561, hereinafter "Stroebel"). In rejecting claims 1, 2, 15-20, 29, 31, and 32, using the same reasons, the Office Action states that the System Guide describes "the use of rate smoothing" and "using/selecting different upward and downward percentages", and that "Stroebel teaches that it is known to use a state detector to detect a predetermined heart rate state or cardiac rhythm state (the time interval between two beats) to activate/select/use the rate smoothing based on whether the state is present to allow the physician to control how much a role rate smoothing should play in controlling the pacing rate." The Office Action then concludes:

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the rate smoothing pacer and method as taught by the System Guide, with an amplifier and a state detector to detect a predetermined heart rate state to activate/select or adjust the rate smoothing based on whether the state is present as taught by Stroebel, since such a modification would provide a rate smoothing pacer that uses an amplify to condition and amplify the cardiac signals so they can be used by the CPU/controller and to use a signal state detector to detect a predetermined heart rate state to activate/select/use the rate smoothing based on whether the state is present, and therefore would activate/select the up and down percentages when activated, to allow the physician to control how much a role rate smoothing should play in controlling the pacing rate.

Appellant traversed, and asserted that this rejection failed to establish a proper *prima facie* case of obviousness. Appellant respectfully submits: (1) The Office Action fails to make a proper *prima facie* case of obviousness because the cited references do not

teach or suggest all the claim limitations; and (2) The Office Action fails to make a proper *prima facie* case of obviousness because it fails to provide a fair suggestion to combine the references.

(1) The Office Action fails to make a proper *prima facie* case of obviousness because the cited references do not teach or suggest all the claim limitations.

Appellant respectfully maintains that the System Guide and Stroebel, each alone or in combination, do not provide the subject matter recited in each of independent claims 1, 16, and 32. The Office Action provides the same reasons to support the rejection of independent claim 1, which recites a system, and independent claims 16 and 32, which each recite a method.

Appellant has been unable to find in the cited portions of the System Guide and Stroebel, each alone or in combination, among other things, any teaching or suggestion of a rate smoothing module configured to select a first rate smoothing percentage and a second rate smoothing percentage of a rate smoothing algorithm based on whether a predetermined state is present, as recited in claim 1.

Appellant has been unable to find in the cited portions of the System Guide and Stroebel, each alone or in combination, among other things, any teaching or suggestion of selecting a first rate smoothing percentage and a second rate smoothing percentage of a rate smoothing algorithm using an implantable system if the state of at least one of a cardiac signal and a physiologic parameter corresponds to a predetermined state, as recited in claim 16.

Appellant has been unable to find in the cited portions of the System Guide and Stroebel, each alone or in combination, among other things, any teaching or suggestion of selecting a first rate smoothing percentage and a second rate smoothing percentage of a rate smoothing algorithm using the implantable system if the state of a cardiac signal corresponds to a predetermined heart rate state, as recited in claim 32.

More specifically, Appellant has been unable to find in the cited portions of the System Guide and Stroebel any teaching or suggestion that their combination necessarily

results in the selection of the “rate smoothing up” percentage—the “first rate smoothing percentage” of claims 1, 16, and 32—based on whether the predetermined state is present. The System Guide relates to rate smoothing with “rate smoothing up” and “rate smoothing down” parameters that can each be independently programmed to “off” or a percentage (i.e., “on” with a programmable percentage) (pages 6-28 and 6-29). The “rate smoothing up” parameter corresponds to the first rate smoothing percentage recited in each of claims 1, 16, and 32. The “rate smoothing down” parameter corresponds to the second rate smoothing percentage recited in each of claims 1, 16, and 32. Stroebel relates to “a rate smoothing capability to prevent large, sudden drop in pacing rate” (column 8, lines 1-3; see also column 2, line 62 to column 3, line 11), and thus relates to the control of the “rate smoothing down” parameter. Given that the “rate smoothing up” and “rate smoothing down” parameters of the System Guide are independently programmable, the combination of these two cited references does not necessarily or inevitably result in a “rate smoothing up” parameter that is activated or selected by using a sensor or a state detector.

The rejection of claims 1, 16, and 32 was traversed in response to a previous Final Office Action, dated November 15, 2005. Subsequently, the Office Action (of February 24, 2006) adds:

In addition, Stroebel does not specifically state that rate increase smoothing should not be used or should be used, but that the sudden rate increase does not “appear” to require smoothing. Therefore Stroebel does not teach against rate increase smoothing and leaves the door open to that possibility. Also, Stroebel is only used to show that it is known to use a sensor to indicate when smoothing should take place to select/use the rate smoothing and not to provide a limit in a pacing rate increase or decrease.

Appellant respectfully traverses this statement and submits that leaving “the door open for [a] possibility” is not a teaching or suggestion of including that possibility.

Moreover, the Office Action admits that “Stroebe1 is only used to show that it is known to use a sensor to indicate when smoothing should take place to select/use the rate smoothing”. Applicant respectfully submits that “use a sensor to indicate when smoothing should take place to select/use the rate smoothing” is not a teaching or suggestion for using a sensor or state detector for selecting both a limit in a pacing rate increase and a limit in a pacing rate decrease.

(2) The Office Action fails to make a proper *prima facie* case of obviousness because it fails to provide a fair suggestion to combine the references.

Appellant respectfully maintains that the cited references fail to suggest the desirability of the combination or modification proposed in the rejection of independent claims 1, 16, and 32. For example, Appellant has been unable to find in the System Guide or Stroebe1, individually or in combination, a suggestion or motivation to modify the device of the System Guide to include the selection of both of its “rate smoothing up” and “rate smooth down” percentages based on whether a predetermined state is present.

In fact, Stroebe1 teaches away from the proposed modification. Stroebe1 relates to “a rate smoothing capability to prevent large, sudden drop in pacing rate”. (Column 8, lines 1-3; see also column 2, line 62 to column 3, line 11). Stroebe1 states:

In general it is considered symptomatic for a patient to experience sudden rate drops so we smooth them. The contrary, sudden rate increase, does not appear to require smoothing.

(Column 8, lines 10-13). Then, the cited portions of Stroebe1 (column 9) discusses prevention of “abrupt downward adjustment in rate”, and “a pacing rate ‘floor’” below which the rate will be smoothed, in contrary to providing a motivation or suggestion to include a limit of pacing rate increase (i.e., the first rate smoothing percentage recited in each of claims 1, 16, and 32).

Appellant respectfully submits that the rejection relies on a conclusory statement without the support of objective evidence of record. The Office Action asserts that the proposed modification “would provide a rate smoothing pacer that ... would

activate/select the up and down percentages when activated, to allow the physician to control how much a role rate smoothing should play in controlling the pacing rate.” However, the Office Action fails to indicate how the cited references or other objective evidence provide the required motivation or suggestion leading to such a conclusion. Leaving “the door open for that possibility” is not a motivation or suggestion.

Summary of Arguments As Applied to Each Claim

The arguments above as applied to the rejected claims 1-6, 15-20, and 28-32 are summarized as follows:

Independent Claim 1 and dependent Claims 2-6 and 15

The rejection does not establish a proper *prima facie* case of obviousness for claim 1. The rejection does not properly show how the cited references teach or suggest all the limitations recited in claim 1. For example, the rejection does not provide objective evidence, using the cited portions of the System Guide and Stroebel, of a system comprising, among other things, “the rate smoothing module configured to select a first rate smoothing percentage and a second rate smoothing percentage of the rate smoothing algorithm based on whether the predetermined state is present, the first rate smoothing percentage limiting a degree of pacing rate increase, the second rate smoothing percentage limiting a degree of pacing rate drop.”

Additionally, the rejection does not provide the required suggestion or motivation for the proposed combination or modification using objective evidence.

Claims 2-6 and 15 depend, either directly or indirectly, on independent claim 1, and are believed to be patentable for at least the reasons provided with respect to claim 1.

Independent Claim 16 and dependent Claims 17-20 and 28-31

The rejection does not establish a proper *prima facie* case of obviousness for claim 16. The rejection does not properly show how the cited references teach or suggest all the limitations recited in claim 16. For example, the rejection does not provide

objective evidence, using the cited portions of the System Guide and Stroebel, of a system comprising, among other things, “selecting a first rate smoothing percentage and a second rate smoothing percentage of a rate smoothing algorithm using the implantable system if the state of the at least one of the cardiac signal and the physiologic parameter corresponds to the predetermined state.”

Additionally, the rejection does not provide the required suggestion or motivation for the proposed combination or modification using objective evidence.

Claims 17-20 and 28-31 depend, either directly or indirectly, on independent claim 16, and are believed to be patentable for at least the reasons provided with respect to claim 16.

Independent Claim 32

The rejection does not establish a proper *prima facie* case of obviousness for claim 32. The rejection does not properly show how the cited references teach or suggest all the limitations recited in claim 32. For example, the rejection does not provide objective evidence, using the cited portions of the System Guide and Stroebel, of a system comprising, among other things, “selecting a first rate smoothing percentage and a second rate smoothing percentage of a rate smoothing algorithm using the implantable system if the state of the cardiac signal corresponds to the at least one predetermined heart rate state.”

Additionally, the rejection does not provide the required suggestion or motivation for the proposed combination or modification using objective evidence.

In General

For reasons provided above, Appellant respectfully requests withdrawal of the §103 rejections of claims 1-6, 15-20, and 28-32, and reconsideration and allowance of these claims.

8. SUMMARY

It is respectfully submitted that claims 1-6, 15-20, and 28-32 are patentable over the cited art. Reversal of the rejection and allowance of the pending claims are respectfully requested.

Respectfully submitted,

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By their Representatives,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS Web, and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 2 day of April, 2006.

Paula Suchy
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Paula Suchy
Signature

CLAIMS APPENDIX

1. A system, comprising:
 - a signal input circuit including at least one of a cardiac sense amplifier adapted to monitor a cardiac signal and a sensor adapted to monitor a physiologic parameter; and
 - a controller circuit, including:
 - a predetermined state detector coupled to the signal input circuit, the predetermined state detector adapted to detect a predetermined state from the at least one of the cardiac signal and the physiologic parameter, the predetermined state including at least one of a heart rate state, a cardiac rhythm state, a patient activity state, a respiration state, and a metabolic need state; and
 - a rate smoothing module, coupled to the predetermined state detector and including at least one rate smoothing algorithm, the rate smoothing module configured to select a first rate smoothing percentage and a second rate smoothing percentage of the rate smoothing algorithm based on whether the predetermined state is present, the first rate smoothing percentage limiting a degree of pacing rate increase, the second rate smoothing percentage limiting a degree of pacing rate drop.
2. The system of claim 1, wherein the signal input circuit includes at least one cardiac sensing electrode.
3. The system of claim 1, wherein the predetermined state detector includes a comparator having a heart rate input and a predetermined threshold input, and a comparator output representative of the predetermined state.
4. The system of claim 3, wherein the predetermined state is a high heart rate that exceeds the predetermined threshold.

5. The system of claim 3, wherein the predetermined threshold is a predetermined threshold window being a predetermined heart rate range, and the predetermined state represents the heart rate in the predetermined heart rate range.

6. The system of claim 3, wherein the heart rate is an atrial heart rate.

15. The system of claim 1, wherein the second rate smoothing percentage is set independently of the first rate smoothing percentage.

16. A method, comprising:

monitoring at least one of a cardiac signal using a cardiac sense amplifier of an implantable system and a physiologic parameter using a sensor of the implantable system;

determining whether a state of the at least one of the cardiac signal and the physiologic parameter corresponds to a predetermined state including at least one of a heart rate state, a cardiac rhythm state, a patient activity level state, a respiration state, and a metabolic need state using the implantable system; and

selecting a first rate smoothing percentage and a second rate smoothing percentage of a rate smoothing algorithm using the implantable system if the state of the at least one of the cardiac signal and the physiologic parameter corresponds to the predetermined state, the first rate smoothing percentage limiting a speed of pacing rate increase, the second rate smoothing percentage limiting a speed of pacing rate drop.

17. The method of claim 16, wherein monitoring the at least one of the cardiac signal and the physiologic parameter includes monitoring a cardiac signal, and the determining includes determining whether a heart rate exceeds a predetermined threshold.

18. The method of claim 17, wherein the heart rate includes an atrial heart rate.

19. The method of claim 16, wherein monitoring the at least one of the cardiac signal and the physiologic parameter includes monitoring a cardiac signal, and the determining includes determining whether the heart rate falls within a predetermined range of heart rates.

20. The method of claim 19, wherein the heart rate includes an atrial heart rate.

28. The method of claim 16, wherein selecting a rate smoothing algorithm if the state of the at least one of the cardiac signal and the physiologic parameter corresponds to the predetermined state includes using a look-up table to map a rate smoothing algorithm to the predetermined state.

29. The method of claim 16, wherein selecting the first rate smoothing percentage and the second rate smoothing percentage comprises selecting the first and the second rate smoothing percentages based on the determined state.

30. The method of claim 29, wherein selecting the first and the second rate smoothing percentages includes using a look-up table to map the first and the second rate smoothing percentages to the predetermined state.

31. The method of claim 16, wherein selecting the rate smoothing algorithm if the state of the at least one of the cardiac signal and the physiologic parameter corresponds to the predetermined state includes selecting based on at least one of a heart rate and an activity level.

32. A method, comprising:
monitoring a cardiac signal using a cardiac sense amplifier of an implantable system;

determining whether a state of the cardiac signal corresponds to at least one predetermined heart rate state using the implantable system; and

selecting a first rate smoothing percentage and a second rate smoothing percentage of a rate smoothing algorithm using the implantable system if the state of the cardiac signal corresponds to the at least one predetermined heart rate state, the first rate smoothing percentage limiting a speed of pacing rate increase, the second rate smoothing percentage limiting a speed of pacing rate drop.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.